Response to Comments Received Regarding Federal Guidance Report No.13 - Part 1, Interim Version: *Health Risks From Low-Level Environmental Exposure to Radionuclides,* EPA 402-R-97-014 (January 1998), During the Public Comment Period, April 13, 1998 through June 30, 1998

U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
Radiation Protection Division

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INTRODUCTION

The Environmental Protection Agency (EPA) published Federal Guidance Report No.13 - Part 1, Interim Version: *Health Risks From Low-Level Environmental Exposure To Radionuclides*, (EPA 402-R-97-014) in January 1998. This technical report contains tables of risk coefficients (risk per unit intake or unit exposure) and information on their use and how they were calculated for a selected list of potentially significant radionuclides in environmental assessments. The report was intended for interim use and to allow public comment on its contents during the period April 13, 1998 through June 30, 1998. The Agency received over 50 commentaries, most containing a number of individual comments, from other Government agencies and the public before the end of the comment period. Some of the Federal commentaries predate the public comment period. This document summarizes these comments and presents the Agency's response to them.

Organization of This Document

This document is divided into two sections. The first section identifies the commenters and, where appropriate, their affiliation. Commentary identification numbers were assigned to each commentary included in EPA Docket A-98-11. Table 1 shows the number assigned to each commentary and the name of the individual making the comments. Some duplicate sets of comments were received. These duplicate commentaries are identified in Table 1. A total of 57 commentaries were received of which 7 were duplicate copies.

Table 2 groups the sources of the commentaries within nine categories. These source categories are: 1) Federal Agencies, 2) Health Care Industry, 3) General Public, 4) Nuclear Power Industry, 5) Other Nuclear Industry, 6) Environmental Groups, 7) Health Physics Society, 8) State Agencies, and 9) Universities. The table also indicates the number of commentaries (omitting duplicates) assigned to each category.

The second section of the report presents 30 summaries of similar comments. Each comment summary is followed by a listing of the commentary numbers from Table 1 which stated essentially that point of view. This summary is followed by EPA's remarks (if any) and the Agency's response to the comment summary.

COMMENT CATEGORIZATION

Table 1. Commentary Identifiers from FGR 13 Docket

Organization / Person	EPA Commentary Id. No.
University of California at Berkeley / Paul Lavely	IV-D-1
Joseph P. Ring	II-D-2
Nuclear Energy Institute / Lynnette Hendricks	IV-D-3
GlaxoWellcome / Thomas Cecich	IV-D-4
Health Physics Society / Otto Raabe	IV-D-5
University of California (National Laboratories) / Howard K. Hatayama	IV-D-6
Texas Radiation Advisory Board / Jack S. Krohmer	IV-D-7
Gordon M. Lodde	IV-D-8
Defense Special Weapons Agency / D. M. Schaeffer	IV-D-9
Defense Special Weapons Agency / D. M. Schaeffer	IV-D-9a (dup of IV-D-9)
Wisconsin Public Service Corporation / Mark Reinhart & Barth J. Wolf	IV-D-10
Beverly A. Good	IV-D-11
Roger P. Shaw	IV-D-12
Texas Radiation Advisory Board / Michael S. Ford	IV-D-13
Gary Parker	IV-D-14
Frank L. Bordell	IV-D-15
University of Washington / David Bodansky	IV-D-16
Floyd W. Wilcox	IV-D-17
Arizona State University / Kenneth L. Mossman	IV-D-18
Michael Campbell	IV-D-19
Thomas Mohaupt	IV-D-20
P. Andrew Karam	IV-D-21

Table 1. Commentary Identifiers from FGR 13 Docket, Continued.

Organization / Person	EPA Commentary Id. No.
Nuclear Regulatory Commission / William F. Kane	IV-D-22
Nuclear Regulatory Commission / Carl J. Paperiello	IV-D-23
Nuclear Regulatory Commission / Carl J. Paperiello	IV-D-24
Nuclear Regulatory Commission / Hugh L.Thompson	IV-D-25
Nuclear Regulatory Commission / Hugh L. Thompson to Dick Wilson	IV-D-26
Nuclear Regulatory Commission / Hugh L. Thompson	IV-D-27
University of California at Los Angeles / Carol S. Marcus	IV-D-28
B. Scott Davidson to Senator Rick Santorum, response from Larry Weinstock to Senator Santorum	IV-D-29
Larry Weinstock to Senator John Glenn	IV-D-30
Larry Weinstock to B. Scott Davidson, response to letter written from B Scott Davidson to Senator Arlen Specter	IV-D-31
Nuclear Regulatory Commission / Hugh L. Thompson	IV-D-32 (dup of IV-D-25)
Nuclear Regulatory Commission / William F. Kane	IV-D-33 (dup of IV-D-22)
Dick Wilson to Hugh L. Thompson, Nuclear Regulatory Commission	IV-D-34
American Petroleum Institute / G. William Frick	IV-D-35
A. John Ahlquist	IV-D-36
ICN Pharmaceuticals / David J. Kruegar	IV-D-37
Council on Radionuclides and Radiopharmaceuticals (CORAR) / Leonard R. Smith	IV-D-38
American Petroleum Institute / G. William Frick	IV-D-39 (dup of IV-D-35)
Health Physics Society / Otto Raabe	IV-D-40 (dup of IV-D-5)

Table 1. Commentary Identifiers from FGR 13 Docket, Continued.

Organization / Person	EPA Commentary Id. No.
Radioactive Waste Management Associates / Marvin Resnikoff	IV-D-41
Hoffmann-La Roche Inc. & Affiliates / Hugh J. Tole	IV-G-1
Health Physics Society, Power Reactor Section / Michael J. Russell, CHP	IV-G-2
American Petroleum Institute / G. William Frick	IV-G-3 (dup of IV-D-35,-39)
American College of Nuclear Physicians (ACNP) & Society of Nuclear Medicine (SNM) / James W. Fletcher, MD	IV-G-4
Tennessee Valley Authority (TVA) / Mark J. Burzynski	IV-G-5
Wesley R. Van Pelt	IV-G-6
Leonard Earls	IV-G-7
EOP GROUP / Joseph S. Hezir	IV-G-8
Chuong Ha	IV-G-9
F. Mark	IV-G-10
Centers for Disease Control and Prevention / Jim Smith	IV-G-11
Department of Energy / Raymond F. Pelletier	IV-G-12
John B. Steward & Michael W. Lantz	IV-G-13
Steve Maheras	IV-G-14
Tennessee Valley Authority (TVA) / Mark J. Burzynski	IV-G-15 (dup of IV-G-5)

Table 2. Comments on FGR 13 by Organization.

Organization	Commentary Id. Number (IV-D-x or IV-G-x) ( ) indicates duplicate	Number of Commentaries
Federal Agencies		10
Nuclear Regulatory Commission	D-22(33), -23, -24, -25(32), -26, -34, -27	
Defense Special Weapons Agency	D-9 (9a)	
Centers for Disease Control and Prevention	G-11	
Department of Energy	G-12	
Health Care Industry		3
GlaxoWellcome	D-4	
Hoffmann-La Roche Inc.	G-1	
American College of Nuclear Medicine	G-4	
General Public	D-2, -8, -11, -12, -14, -15, -17, -19, -20, -21, -29, -30, -31, -36, G-6, -7, -9, -10, -13, -14	20
Nuclear Power Industry		3
NEI	D-3	
Wisconsin Public Service	D-10	
TVA	G-5(15)	
Other Nuclear Industry		4
American Petroleum Institute	D-35(D-39, G-3)	

Table 2. Comments on FGR 13 by Organization, Continued.

Organization	Commentary Number (IV-D-x or G-x) ( ) indicates duplicate	Number of Commentaries
Other Nuclear Industry, Continued		
ICN Pharmaceuticals, Inc.	D-37	
EOP GROUP	G-8	
CORAR	D-38	
Organized Environmental Groups		1
Radioactive Waste Management Associates	D-41	
Health Physics Society	D-5(D-40), G-2	2
State Agencies		2
Texas Radiation Advisory Board	D-7, 13	
Universities		5
University of California	D-1(Berkeley), D-6 (National Laboratories), D-28(Los Angeles)	
University of Washington	D-16	
Arizona State University	D-18	

COMMENT SUMMARIES AND EPA RESPONSE

Summary: **It does not appear that EPA has followed the statutory mandate to consult outside qualified scientists and experts in radiation matters, such as the President of the National Academy of Sciences and Chairman of the National Council on Radiation Protection and Measurements. Additionally, 42 U.S.C. Section 4365(e) requires that any proposed criteria document, standard limitation, or regulation under any authority of the Administrator is required to be submitted to the Science Advisory Board. The Reviewer is not aware if EPA has complied with this requirement.**
[G-8]

Response: Federal Guidance Report Number 13 does not represent new Federal Guidance, *per se*. Rather it is a technical report that provides consistent methods for assessing the cancer risk from exposure to radionuclides. While there is no statutory mandate to consult with recognized experts outside the Agency, EPA did conduct an external peer review of the report, consistent with Agency policy. The document has also been reviewed by the EPA Science Advisory Board (SAB) and the final version will reflect the SAB's comments.

Summary: **Federal Guidance Report Number 13 should not be finalized since the other Federal Agencies have not concurred in the report.**
[D-36]

Response: Federal Guidance Report 13 is a technical report and does not constitute radiation protection guidance approved by the President. Such guidance, prepared by the Agency under the Federal Radiation Council (FRC) authority that was transferred to EPA by Reorganization Plan No. 3 of 1970, is reviewed by the Office of Management and Budget (OMB) prior to Presidential approval. A thorough consideration of comments and recommendations by other Federal agencies would be an integral part of the approval process for such Presidential guidance.

To assist Federal and other agencies in the development and implementation of radiation protection regulations, EPA has issued a series of technical reports designated as Federal Guidance Reports. Federal Guidance Report No. 13 is intended for use in assessing risks from radionuclide exposure for a variety of applications ranging from analyses of specific sites to the general analyses that support rule making. Its use by Federal agencies is encouraged to promote consistency in risk

assessment, however, such use is discretionary. Although formal concurrence by other Federal agencies is not required, all Federal Guidance technical reports are developed in consultation with interagency work groups. EPA takes seriously the comments and concerns of the other Federal agencies and will continue to give them careful consideration in preparing the final version of the document.

Summary: **The EPA's authority under Reorganization Plan No. 3 is limited to establishing standards for radiation exposure in the environment for the protection of the public outside the boundaries of locations under the control of persons possessing or using radioactive material. The EPA should limit the scope of Federal Guidance Report 13 to the non-work place environment and should not apply it to occupational exposures.**
[G-8]

Response: While EPA's standard setting authority is limited to those exposures outside the control of persons possessing or using radioactive material, its Federal Guidance authority to recommend guidance for all Federal Agencies to the President is not so limited. Such Presidential Guidance has already been issued for limits on occupational exposure.

However, EPA does agree that the risk factors of Federal Guidance Report 13 are not expected to be appropriate for occupational exposure cases. The risk coefficients are based on the premise of a mix of population age and gender that is reflective of the total U.S. population. It would be difficult to imagine an occupationally involved group that would reflect this same mix of characteristics.

Summary: **The commenters support the linear, no-threshold model.**
[D-16, D-41, G-11]

Remarks: The commenters indicate their basic agreement with the use of the linear, no-threshold (LNT) model as a basis for calculating estimates of risk. Various reasons for the support were given including that it can be considered reasonably conservative, and that it has been recommended by various authoritative bodies. One commenter suggested that the dose and dose rate reduction factor (DDREF) used in the report should be more conservative and recommended that a factor of 1, i.e. no reduction should be used for all cancer sites.

Response: EPA agrees that the use of the LNT model is the most prudent model for risk assessment and that its use is consistent with National and International advisory bodies. Similarly, EPA has chosen to use a DDREF of 2 in accordance with the most conservative value of the range recommended by the National Academy of Sciences Committee on Biological Effects of Ionizing Radiation, and in accordance with the recommendations of the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP).

Summary: **The commenters are opposed to the use of the linear, no-threshold model. [D-1, D-3, D-4, D-5, D-10, D-11, D-12, D-14, D-17, D-18, D-19, D-20, D-21, D-28, D-29, D-35, D-37, G-1, G-4, G-7, G-8, G-10, G-12]**

Remarks: The point of view that the LNT model is inappropriate for estimating risks at all levels was expressed by a number of commenters. The comments indicated numerous considerations in support of this contention. A prominent theme was that research indicates that cancer-induction dose response relationships are non linear with an effective threshold at relatively high doses. Other commenters noted that there was no evidence in population epidemiological studies that there is any detrimental effect at low environmental doses. Some indicated that there is a growing body of evidence for stimulatory effects at low doses, a phenomenon referred to as hormesis, that may even be beneficial.

Response: The Agency's choice of a LNT model for radiation carcinogenesis is not new. It is the policy of the Federal government and EPA has used a LNT model, modified by a dose and dose rate reduction factor, for all of its recent standards. The basis for this choice was clearly stated in the promulgation of the Agency's standards for "Radiation Protection for Nuclear Power Operations" (40 CFR 190) in the Federal Register of May 29, 1975 (volume 40 number 104, page 23420). In 1976, in conjunction with the Agency's promulgation of National Interim Primary Drinking Water Regulations, a policy statement was issued describing the reasons and basis for the use of an LNT model in establishing radiation protection standards. The use of the LNT model is also included in The January 1987 *Radiation Protection Guidance to Federal Agencies for Occupational Exposure; Recommendations Approved by the President*. Federal Guidance Report Number 13 merely implements this already existing Federal policy. It should be understood that Federal Guidance Report 13 primarily represents a compilation of the linear slopes of risks versus intakes of radionuclides (*i.e.*, risk coefficients) based on the LNT model. Since there is no conclusive basis for any specific threshold level, the lines must intersect the origin of zero risk at zero incremental dose

above the natural background dose. No implications of accuracy or uncertainty are to be inferred by expressing the risk coefficient in the SI unit of activity (becquerel), rather than any other unit of activity.

EPA realizes that opinion continues to be divided on how to extrapolate from the observed health effects (e.g., cancer) of radiation (mostly at higher doses than those normally encountered) to estimate the most probable effects of the doses actually encountered by members of the public. Most scientists believe that the available data justify the use of a linear, no-threshold model for estimating the carcinogenic risk of low doses. Some scientists, however, believe that such a model may provide significant underestimates or overestimates of such effects.

Continuing studies have resulted in increased estimates (roughly threefold between 1972 and 1990) of the probable risk of cancer from environmental levels of radiation largely due to the increased follow up time of the exposed populations. Nonetheless, the estimated number of health effects induced by incremental doses of radiation comparable to natural background levels remains small enough, relative to the number that already occur from other causes, that in all likelihood it will never be possible to detect them in human epidemiological studies. This lack of detectability does not mean, however, that such effects on health do not occur. In the absence of reliable evidence to the contrary, the Agency believes that it is appropriate, for radiation protection purposes, to assume that at and just above the level of natural background, the risk of cancer increases linearly with increasing dose, without a threshold. That is, we assume that any increase in exposure to ionizing radiation carries the potential for causing harm to health. This assumption is consistent with current as well as historical practice for radiation protection world wide.

EPA will continue to support the evaluations of available biological data, principally through its continuing involvement with the National Academy of Sciences - National Research Council, Committee on Biological Effects of Ionizing Radiation. EPA also continues to monitor the activities of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the ICRP and the NCRP in their evaluations of the effects of ionizing radiation. As new scientific evidence becomes available, EPA will consider its effect on the relationship between exposure and risk and will update its reports and regulations appropriately.

Summary: **The EPA application of the linear, no-threshold model is inconsistent with the ICRP and NCRP advisories and U.S. Federal Guidance.**
[D-2, D-3, D-4, D-5, D-37, D-38, G-4, and G-5]

Remarks: The commenters feel that the EPA approach of applying the LNT model directly to a radionuclide intake or external exposure is contrary to the advisories of the ICRP and the NCRP.

There was also a point of view that the calculation of age related risks based on dose models from the ICRP Publication 56 series of reports is inappropriate since the dose models used to prepare Federal Guidance Report 11 are based on ICRP Publication 30.

Response: There are no ICRP or NCRP prohibitions about using the LNT model for population risk assessments at low doses. NCRP Report 116, *Limitation of Exposure to Ionizing Radiation*, does recommend that an annual effective dose of 0.01 mSv be considered a Negligible Individual Dose per source or practice. NCRP report 116 also notes that previous recommendations (Report 97 *Recommendations on Limits for Exposure to Ionizing Radiation*) of excluding individuals with 0.01 mSv or less from collective dose evaluations was being withdrawn, although they do note that it may not be cost effective. They go on to note, however, that "[W]e can not exclude the possibility of a fatal cancer attributable to radiation in a very large population of people exposed to very low doses of radiation...."

The radionuclide dose coefficients from Federal Guidance Reports 11 and 12 are widely used in the implementation of regulations. The dose coefficients in these reports are consistent with recommendations in ICRP Publications 26 and 30. The risk coefficients in Federal Guidance Report 13 will not change the use of Reports 11 and 12 in any way.

Summary: **The EPA should add a qualifying statement on the use of the LNT model, including the fact that it has not been scientifically validated, and that there may or may not be zero risk for exposure to very low levels of radiation.**
[D-1, D-3, D-10, D-11, D-12, D-21, G-8, and G-12]

Remarks: These commenters, all of whom were also among those that opposed the use of the LNT model as the basis for the reports tables, feel that if a final version of the report is to be issued, it should include additional qualifying statements on the issues of the LNT debate.

Response: EPA agrees that these issues should be addressed in the report. The final version of the report will emphasize that the cancer risk coefficients are based on the LNT model and will address the differences of view that exist on the validity of that approach.

Summary: **The reviewer strongly suggests that Federal Guidance Report No. 13 address some of the more credible evidence contrary to the LNT theory.**
[G-8]

Response: In the final report, EPA will include more discussion of the differences in view on the use of the linear, no-threshold model. Other methods of extrapolation to the low-dose region could yield higher or lower numerical estimates of cancer deaths. Studies of human populations exposed at low doses are inadequate to demonstrate the actual level of risk. There is scientific uncertainty about cancer risk in the low-dose region below the range of epidemiological observation, and the possibility of no risk cannot be excluded.

Summary: **Federal Guidance Report Number 13 does not agree with the Health Physics Society Position Statement against estimating risks for exposures less than 10 rem.**
[D-1, D-2, D-3, D-5, D-9, D-10, D-17, D-21, D-35, D-37, D-38, G-1, and G-4]

Remarks: The Health Physics Society Position Statement recommends against quantitative estimation of health risks below an individual dose of 5 rem in one year or a lifetime dose of 10 rem in addition to background radiation. The Society statement indicates that below 10 rem (which includes occupational and environmental exposures), risks of health effects are either too small to be observed or are non-existent. The statement also indicates that biological mechanisms, including cellular repair of radiation injury, are not accounted for by the linear, no-threshold model.

Response: The Health Physics Society Position Statement, which was formulated by the Society's Scientific and Public Issues Committee, was not accompanied by any new information or new scientific evaluation of available biological effects information. The Statement is, rather, the considered opinion of the committee members. In contrast, the EPA utilization of the LNT model is supported by a large body of recognized experts. As generally stated in the discussion of the LNT model itself, it is this body of scientific review that the Agency must look to for direction. The Agency recognizes, and acknowledges, that effects at low doses may not currently be scientifically discernible from those due to other causes, but this does not mean they do not exist. Furthermore, it should be recognized that the Agency model incorporates a dose and dose rate reduction factor (DDREF) to account for some measure of greater efficacy of biological repair and other ameliorating considerations that may be associated with these lower exposures.

Summary: **The report should provide a more comprehensive discussion of uncertainty and should include quantitative estimates of the uncertainty range for the risk coefficients.**
[D-4, D-5, D-6, D-8, D-9, D-10, D-11, D-12, D-13, D-15, D-18, D-19, D-22, D-25, D-35, D-38, G-2, G-4, G-5, G-6, G-7, G-8, G-10, G-11, and G-12]

Remarks: The view that the uncertainty analysis in the interim version of the report is insufficient was widely held. Several commenters felt that all the table values should be expressed as an uncertainty range that included zero as the lower limit. Others indicated that a quantitative analysis of uncertainty should be presented of all the facets of the analysis. Some felt that the report did not meet EPA's own guidance for consideration of uncertainties. One commenter noted that some references for the uncertainty discussion had not yet been published.

Response: EPA appreciates these concerns and, hence, has substantially strengthened the treatment of uncertainty in preparing material for the final version of the report. The subject will be addressed in both the text of the report and more comprehensively in an appendix. The appendix will discuss in some detail the sources of uncertainty in calculating the radionuclide cancer risk coefficients. The risk coefficient tables in the final report will also include judgments concerning the risk coefficient uncertainties for several important radionuclides and exposure modes. All the uncertainty references are expected to be in the public domain by the time the final report is published.

Summary: **EPA should only consider dose based regulations so that risk based assessment models are not needed. Otherwise inconsistencies in assessment of risk and dose within EPA and between federal agencies will increase.**
[D-3, D-4, D-5, D-6, D-25, D-36, D-38, G-1, G-4, G-7, and G-13]

Remarks: Several commenters see the development of Federal Guidance Report 13 as damaging the Federal agencies cooperative efforts in a manner that would be detrimental to the regulated community. One perception on how to avoid this would be for EPA to consider only dose standards and not to perform any analysis of risk.

Response: Although EPA's radiation protection regulations may be expressed in terms of a dose or concentration, consideration of cancer risk is an essential part in setting such levels. As an agency that deals with many carcinogenic substances, the obvious common denominator is risk. The risk

averted that is associated with the proposed regulation is an important consideration in the Agency's decisions. This is particularly true in those arenas where radioactive constituents are only one of many that are being regulated under a particular statute. In many cases the law itself requires that the "risk" be estimated and limited. Federal Guidance Report Number 13 will assist in assuring a uniform basis for such evaluations.

Summary: **FGR 13 does not provide dose coefficients calculated using its dose models for comparison with those tabulated in FGR 11.**
[D-16]

Response: Since FGR 13 does not update or affect the use of FGR 11, to include tables of dose coefficients could be misleading as to the intent of FGR 13. Dose coefficients using the dose models of FGR 13 are tabulated in ICRP Publication 72.

Summary: **Include Dose and Annual Limit on Intake Tables and F (fast dissolution and a high level of absorption to blood), M (intermediate rate of dissolution and intermediate level of absorption to blood), S (slow dissolution and a low level of absorption to blood) differences for inhalation. Point out the difference between FGR 11 and FGR 13.**
[D-16, G-9]

Response: Inclusion of tables of dose coefficients and Annual Limits on Intake (ALI) is outside the scope of FGR 13.

Consideration of the extent of absorption of a radionuclide from the respiratory tract to the blood is discussed in FGR 13. For each of the elements addressed in the ICRP's series on doses to the public from intake of radionuclides, a recommendation is made by the ICRP concerning a default absorption type to be used in the absence of specific information (ICRP Publication 72). For each radionuclide, Table 2.1, "Mortality and morbidity risk coefficients for inhalation," provides the risk coefficient calculated for each absorption type and also indicates the default type.

The differences between FGR 11 and FGR 13 are discussed in the response to the previous comment.

Summary: **Acute and chronic risk factors should be differentiated.**
[D-11, D-12]

Response: For radionuclide exposures that result in doses in the low dose, low dose rate range, the average risk to an individual from an acute exposure and the risk to an average individual to a chronic (life time) exposure have the same value. Appendix D of the interim version considers the adjustment of risk coefficients for a short-term exposure to a population with the current U.S. age distribution. As a practical matter, the adjustment ranges are too small to justify tabulating a separate set of risk coefficients for that application. As stated in the Preface and Introduction, FGR 13 should not be used to assess high acute exposures.

Summary: **The FGR 13 should include Rn and Rn daughters or other natural radionuclides in the risk coefficient tables.**
[D-16, G-2, G-13]

Response: The final version of FGR 13 will contain risk coefficients for essentially all the radionuclides for which dose coefficients are tabulated in FGR 11 and FGR 12. EPA is presently developing a new model to assess lung cancer risk from exposure to radon decay products and has decided not to include a risk coefficient based on its current model. ICRP Publication 72 does not provide dose models for inhalation of radon or other noble gases. Risk coefficients for these exposures may be incorporated into a subsequent Federal Guidance technical report.

Summary: **All risk coefficients are based on one particle size (1 micron Activity Median Aerodynamic Diameter or AMAD). The tables should include risk coefficients for other size AMAD particles.**
[D-8, G-9]

Response: A 1 μm (AMAD) particle size is recommended by the International Commission on Radiological Protection for consideration of environmental exposures in the absence of specific information about the physical characteristics of the aerosol. In the final report, the table of inhalation risk coefficients for particle size 1 μm will address about 800 radionuclides and various absorption types and will be about 60 pages long. FGR 13 would become unwieldy if risk coefficients were included for additional particle sizes.

Summary: **The age- and gender-specific risk coefficients should be included in the tables of the report.**
[D-41, G-14]

Response: FGR 13 would become unwieldy if age- and gender-specific risk coefficients were included in the tables in the report. Age- and gender-specific risk coefficients will be available on CD-ROM when the final report is released.

Summary: **The report should add a caveat that coefficients are not for a specific individual.**
[G-12]

Response: The Introduction to FGR 13 ("How to apply a risk coefficient") states that the risk coefficients may be used to assess *per capita* (population-averaged) risk. The Introduction to FGR 13 ("Limitations on use of the risk coefficients") states that "analyses involving the risk coefficients...should be limited to estimation of prospective risks in hypothetical or large populations" and that the risk coefficients "are not intended for application to specific individuals and should not be used for that purpose."

Summary: **The technical assumptions forming the basis for EPA's estimated cancer risk coefficients have not been subjected to appropriate scientific review and need to be verified and validated before publication.**
[D-22, G-8]

Response: With minor exceptions fully explained in the interim report, the technical assumptions related to biokinetic and dosimetric models and methods are those of the International Commission on Radiological Protection, and those concerning cancer risk per unit dose were published in 1994 in EPA Report 402-R-93-076 and have been used by the EPA since that time. The Preface to the interim report (page iv) states that EPA has issued FGR 13 "as an interim report at this time in order to provide governmental agencies and other interested parties an opportunity to become familiar with it and its supporting methodology and to provide comments for the Agency's consideration before publishing the final version." As stated in the Preface, the preparation of the interim version of FGR 13 was funded by EPA, DOE, and NRC, and its content was reviewed by these agencies. The Preface also indicates the individuals involved in the external review of the document. The interim

version of the report has been reviewed in depth by the Radiation Advisory Committee of EPA's Science Advisory Board, and the results of that review will be reflected in the final report.

Chapters 3 through 7 of the report describe the models and assumptions used in calculating the risk coefficients. References are provided in these chapters indicating the published sources of the models and their assumptions.

Summary: **The reviewer did not receive the promised CD-ROM. The CD-ROM is needed so that the reviewer can view all of the supporting documentation that was used by EPA in drafting FGR 13.**
[D-25, G-8, G-14]

Response: EPA will make the CD-ROM available when the final report is released.

Summary: **Important National Academy of Sciences and DOE studies are ongoing, so the EPA should wait until more research is done before issuing the report.**
[D-35, D-37, G-8]

Response: In this important field, studies will always be ongoing as more is learned about the effects of radiation. EPA believes that sufficient studies have been completed to justify publication of FGR 13 at this time.

Summary: **FGR 13 should incorporate the latest RERF data from the Japanese bomb survivor study.**
[D-41]

Response: FGR 13 does incorporate RERF data available at the time the radiation risk models were chosen. EPA acknowledges that this does not include the most recent mortality and incidence data from RERF. Together with other Federal agencies, the EPA is sponsoring a study by the National Research Council that will assess the latest RERF data along with data from other sources relevant to radiation risk estimation. It is anticipated that, following publication of that report, EPA will revise its risk estimates. Some changes might be made prior to that time if clearly warranted by new information.

Summary: **FGR 13 will force lower regulatory limits, especially on Federal Agencies, which will result in rule-making and enforcement of standards (e.g., new Maximum Contaminant Levels for radionuclides in drinking water) that are considerably lower than those previously proposed on dose-based methods.**
[D-1, D-5, D-15, D-21, D-25, D-28, D-38, D-41, G-8, G-10]

Response: Most Federal radiation protection regulations are dose based and will not be affected by FGR 13. Cleanup levels calculated with FGR 13 risk coefficients to meet a specific risk goal can be less stringent than those based on older models and methods.

Summary: **The theoretical number of lives saved compared to the costs that would be involved in using standards based on risks in Federal Guidance Report 13 do not justify its use in cost effectiveness assessments.**
[D-1, and D-28]

Response: It would be inappropriate to prejudge the results of any cost effectiveness analysis. The magnitude of the risk coefficient is only one factor in such an analysis. Indeed a cost effectiveness analysis might be an ideal place for the use of the risk coefficients.

Summary: **The EPA is demonstrating bias in favor of opponents of nuclear technology, because the FGR 13 will add to public fear concerning nuclear technology, thereby contributing to the shutdown of existing nuclear power plants and committing the U.S. to rely upon fossil fuel power plants that contribute to air pollution problems.**
[G-2]

Response: EPA's approach is to evaluate all energy sources on the basis of their environmental impacts. The risk evaluation basis used in FGR 13 is the same as that applied by all Federal agencies in developing radiation regulations. It is also very much the same as EPA uses for all carcinogens regardless of the source.

Summary: **There is a high potential for misuse of the report and examples are given to show how such misuse could occur.**
[D-1, D-7, D-10, D-13, D-14, D-15, D-17, D-20, D-21, D-28, D-29, D-35, D-37, D-38, G-1, G-2, G-4, G-7, G-13]

Response: The potential for misuse exists with any database associated with a complex subject such as a risk assessment. The introduction to the report discusses the general basis for the coefficients, how to apply them, limitations on their use, and their uncertainties. Other chapters in the report describe in detail the models and assumptions used to derive the risk coefficients. This supporting information is intended to provide the user with the information needed to make an informed use of the risk coefficients The final version will continue to address these issues.

Summary: **Society could make better use of the money that will be spent assessing radiation exposures and enforcing compliance with the new radiological standards that will be imposed based on Federal Guidance Report 13.**
[D-28, D-37, D-38, G-1, and G-4]

Response: Radiation protection standards have consistently been set with a consideration of risk. EPA believes Federal Guidance Report No.13 will strengthen the scientific basis for such risk estimates and should make that process much more evident and transparent to those interested in the basis of the determination. In any case, risk assessment is only one consideration in the regulatory process.

Summary: **The stated precision for the risk coefficients is too high, three significant digits is too many and should be limited to one significant number.**
[D-3, D-11, D-12, D-15, D-17, D-20, D-37]

Response: The risk coefficients in this technical report are intended to be used in an intermediate calculational step in performing a risk assessment. The interim version of FGR 13 states, on page 11, that values are tabulated to three decimal places "to facilitate comparisons as well as conversion to other units" and that "no indication of uncertainty is intended or should be inferred from this practice." EPA expects that a person performing a risk calculation will round the final results appropriately. Truncating the values at intermediate steps in the calculation can introduce significant

calculational error. It should be noted that the dose coefficients in FGR 11 and 12 are also tabulated with three significant figures.

Summary: **The definitions of "activity" and "becquerel" in the glossary should be modified for the lay reader.**
[D-36]

Response: EPA has decided to retain the present definitions of "activity" and "becquerel" to be consistent with those published in the International Commission on Radiation Units and Measurements (ICRU) Report 60.

Summary: **The table column "% total mortality" in Tables 2.1, 2.2, et al. could be misunderstood. The casual reader could be led to conclude that it is the rate of death from intake of a specific material.**
[G-13]

Response: This column has proved confusing and will be removed from these tables.